IMPLEMENTATION REQUIREMENTS ON QUALITY MANAGEMENT SYSTEM (QMS) AND TRACEABILITY FORM

This implementation on REQUIREMENTS ON QUALITY MANAGEMENT SYSTEM (QMS) AND TRACEABILITY FORM applies to new medical device applications and re-registration medical device applications submitted from 1 January 2024.

Local Manufacturer

- **ISO 13485** accept for **Class A, B, C, D.**

Foreign Legal Manufacturer

- **ISO 13485** accept for **Class A, B, C, D.**
- **US Quality System (QS) regulation (21 CFR Part 820)** accept for **Class A, B, C, D.**
- **Japan MHLW Ordinance 169** accept for **Class A, B, C, D.**
- **ISO 9001** accept for **Empty Gas Cylinder** only.

- **Declaration of Traceability of Evidence of Conformity** (to use QMS from manufacturing site/ OEM) accept for **Class A** only

Note : This infographic is referring to the announcement on 4th August 2023.
Updated infographic version on 31st January 2024